

PATENT COOPERATION TREATY

TRANSLATION

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To:

Date of mailing
(day/month/year)

Applicant's or agent's file reference

664678

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/JP2004/012638

International filing date (day/month/year)

01.09.2004

Priority date (day/month/year)

01.09.2003

International Patent Classification (IPC) or both national classification and IPC

Applicant

Earthus, Inc.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/II

Authorized officer

Facsimile No.

Telephone No.

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Box No. 1 Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language
_____, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ in written format

☐ in computer readable form

c. time of filing/furnishing

☐ contained in the international application as filed.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

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Box No. III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claim No. 26

because:

☒ the said international application, or the said claim No. 26
relate to the following subject matter which does not require an international preliminary examination (*specify*):

The subject matter of Claim 26 relates to a method for treatment of the human body by therapy, which does not require an international preliminary search.

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____
are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. _____ are so inadequately supported
by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claim No. 26

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐ has not been furnished

☐ does not comply with the standard

the computer readable form

☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See Supplemental Box for further details.

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Box No. IV

Lack of unity of invention

1. ☐ In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has:
- ☐ paid additional fees
 - ☐ paid additional fees under protest
 - ☐ not paid additional fees
2. ☒ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is
- ☐ complied with
 - ☒ not complied with for the following reasons:

1) Claims 1-25 relate to a composition containing a β -hydroxy short-to-medium chain fatty acid polymer for purposes of transporting a β -hydroxy short-to-medium chain fatty acid or an oligomer thereof to the large intestine.

2) Claims 27-31 relate to a soluble large-intestinal coating comprising a β -hydroxy short-to-medium chain fatty acid polymer.

3) Claims 32-37 relate to a composition containing a β -hydroxy short-to-medium chain fatty acid, an oligomer thereof or a physiologically acceptable derivative of these in a form that can be transported to the large intestine.

These three groups of inventions do not appear to be a group of inventions so linked as to form a single general inventive concept.

4. Consequently, this opinion has been established in respect of the following parts of the international application:

- ☐ all parts
- ☒ the parts relating to claims Nos. 1-25, 27-37

**WRITTEN OPINION OF THE
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Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	16-25, 36, 37	YES
	Claims	1-15, 27-35	NO
Inventive step (IS)	Claims		YES
	Claims	1-25, 27-37	NO
Industrial applicability (IA)	Claims	1-25, 27-37	YES
	Claims		NO

2. Citations and explanations:

Document 1: JP 2002-500027 A
 Document 2: JP 5-503637 A
 Document 3: JP 3-83917 A
 Document 4: JP 63-258810 A
 Document 5: WO 92-16191 A1
 Document 6: JP 2002-521330 A
 Document 7: JP 2001-515510 A
 Document 8: COOK, S.I. et al., Review article: short chain fatty acids in health and disease, *Aliment. Pharmacol. Ther.*, 1998, Vol. 12, pp. 499-507
 Document 9: NIWA, Takahashi et al., Effect of Dietary Fiber on Morphine-induced Constipation in Rats, *Biosci. Biotechnol. Biochem.*, 2002, Vol. 66, No. 6, pp. 1233-1240
 Document 10: MARCIL, Valerie et al., Butyrate Impairs Lipid Transport by Inhibiting Microsomal Triglyceride Transfer Protein in Caco-2 Cells, *J. Nutr.*, July 2003, Vol. 133, pp. 2180-2183

The subject matter of claims 1-3, 5-7, 13 and 14 does not appear to possess novelty or to involve an inventive step because it is described in documents 1-7 cited in the ISR. Claims 1-3, 5-7, 13 and 14 include the description: "for purposes of transporting a β -hydroxy short-to-medium chain fatty acid or oligomer thereof to the large intestine," but this description only indicates a property of the composition, which is a property that any composition containing a β -hydroxy short-to-medium chain fatty acid polymer would have. Compositions containing β -hydroxy butyric acid polymers and other β -hydroxy short-to-medium chain fatty acid polymers are described in all of documents 1-7, which also describe that these compositions are animal feeds and foodstuffs.

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: BOX V. 2

The subject matter of claim 4 does not appear to possess novelty or to involve an inventive step because it is described in documents 1, 2 and 6 cited in the ISR. All of documents 1, 2 and 6 describe compositions containing β -hydroxy short-to-medium chain fatty acid polymers, such as a copolymer of β -hydroxy butyric acid and β -hydroxy valeric acid and the like.

The subject matter of claims 8-10 does not appear to possess novelty or to involve an inventive step because it is described in documents 1, 2 and 4-7 cited in the ISR. All of documents 1, 2 and 4-7 describe that β -hydroxy butyric acid polymers and other β -hydroxy short-to-medium chain fatty acid polymers are produced by microorganisms.

The subject matter of claims 11 and 12 does not appear to possess novelty or to involve an inventive step because it is described in documents 1, 2 and 7 cited in the ISR. All of documents 1, 2 and 7 describe that β -hydroxy butyric acid polymers and other β -hydroxy short-to-medium chain fatty acid polymers are produced by plants.

The subject matter of claim 15 does not appear to possess novelty or to involve an inventive step because it is described in documents 3-7 cited in the ISR. All of documents 3-7 describe drug compositions containing β -hydroxy butyric acid polymers or other β -hydroxy short-to-medium chain fatty acid polymers.

The subject matter of claims 27-31 does not appear to possess novelty or to involve an inventive step because it is described in documents 3-5 cited in the ISR. All of documents 3-5 describe soluble large-intestinal coating compositions containing β -hydroxy butyric acid polymers or other β -hydroxy short-to-medium chain fatty acid polymers.

The subject matter of claims 32, 34 and 35 does not appear to possess novelty or to involve an inventive step because it is described in documents 1-7 cited in the ISR. All of documents 1-7 describe compositions containing β -hydroxy short-to-medium chain fatty acids or oligomers thereof or physiologically acceptable derivatives of these in forms that can be transported to the large intestine.

The subject matter of claim 33 does not appear to possess novelty or to involve an inventive step because it is described in documents 3-7 cited in the ISR. All of documents 3-7 describe drug compositions containing β -hydroxy short-to-medium chain fatty acids or oligomers thereof or physiologically acceptable derivatives of these in forms that can be transported to the large intestine.

The subject matter of claims 16-25, 36 and 37 appears to possess novelty because it is not described in any of the documents cited in the ISR.

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Supplemental Box

Continuation of Box V.2:

The subject matter of claims 16-25, 36 and 37 does not appear to involve an inventive step based on documents 3-5 cited in the ISR. The inventions of claims 16-25, 36 and 37 are used in the prevention and/or treatment of inflammatory bowel disease, colon cancer and the like, which is not described specifically in documents 3-5. However, the compositions containing β -hydroxy short-to-medium chain fatty acid polymers and the compositions containing β -hydroxy short-to-medium chain fatty acids or oligomers thereof or physiologically acceptable derivatives of these in forms that can be transported to the large intestine that are described in documents 3-5 could be contained in a variety of drugs, and could be used for a variety of diseases. Thus, it would be easy for a person skilled in the art to use the compositions described in documents 3-5 for the prevention and/or treatment of inflammatory bowel disease, colon cancer and the like.

The subject matter of claims 16-25, 36 and 37 does not appear to involve an inventive step based on documents 6-10 cited in the ISR. The inventions of claims 16-25, 36 and 37 are used in the prevention and/or treatment of inflammatory bowel disease, colon cancer and the like, which is not described in documents 6 and 7. However, documents 6 and 7 do involve drugs having as active ingredients β -hydroxy short-to-medium chain fatty acids which are produced in the body, while the use of β -hydroxy short-to-medium chain fatty acids for inflammatory bowel disease, colon cancer and the like is described in all of documents 8-10. Thus, it would be easy for a person skilled in the art to use the drugs described in documents 6 and 7 having as active ingredients β -hydroxy short-to-medium chain fatty acids which are produced in the body for inflammatory bowel disease, colon cancer and the like based on the descriptions of documents 8-10.